Attachment B

Revisions Subsequent to Public Hearing and Comment

Proposed Amendments to the Hospital Licensure Regulations (105 CMR 130.000)
105 CMR 130.1400 Primary Stroke Service Licensure Regulations

1) Add a new section (H) to 105 CMR 130.020 Definitions, Essential Health Service, Excluded Services List:
(H) Primary Stroke Service.

2) Add a new section (BB) to 105 CMR 130.020 Definitions, Service:

(BB) Primary Stroke Service. Emergency diagnostic and therapeutic services provided by a multidisciplinary team and available 24 hours per day, seven days per week to patients presenting with symptoms of acute stroke.

3) Add following new sections 105 CMR 130.1400 through 1413: **Deleted:** 2

130.1400: Purpose

The purpose of 105 CMR 130.1400 through 105 CMR 130.1413 is to establish standards for the designation of a Primary Stroke Service in a hospital with licensed Emergency Services. **Deleted:** 2

130.1401: Definitions

Acute Hemorrhagic Stroke (a subtype of Acute Stroke) means the relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Initial CT/MRI may show evidence of acute brain hemorrhage (either intracerebral or subarachnoid blood) or no evidence of blood on imaging in the presence of blood in the subarachnoid space by lumbar puncture.

Acute Ischemic Stroke (a subtype of Acute Stroke) means the relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Initial CT/MRI may show evidence of acute ischemic changes or no evidence of stroke.

Acute Stroke means the relatively rapid onset of a focal neurological deficit with signs or symptoms persisting longer than 24 hours and not attributable to another disease process. Acute stroke includes both ischemic and hemorrhagic stroke, and requires brain imaging to define the stroke subtype.

Acute Stroke Expertise means any of the following: (1) completion of a stroke fellowship, (2) participation (as an attendee or faculty) in at least two regional, national, or international stroke courses or conferences each year, (3) five or more peer-reviewed publications on stroke, (4) eight or more continuing medical education (CME) credits each year in the area of cerebrovascular disease, or (5) other criteria approved by the governing body of the hospital.

Acute Stroke Team means physician(s) and other health care professionals, e.g., nurse, physician's assistant, or nurse practitioner, with acute stroke expertise available for prompt consultation consistent with time targets acceptable to the Department. **Deleted:** rapid

Primary Stroke Service means emergency diagnostic and therapeutic services provided by a multidisciplinary team and available 24 hours per day, seven days per week to patients presenting with symptoms of acute stroke.

Time Targets means time frames established by the Department in an advisory bulletin regarding Primary Stroke Services.

130.1402: Application to Provide Primary Stroke Service

Each hospital seeking designation as a provider of a Primary Stroke Service shall submit an application to the Department, on forms prescribed by the Department, documenting how the hospital will meet the standards in 105 CMR 130.1400 through 130.1413.

130.1403: Evaluation of an Application

The Department shall designate a Primary Stroke Service upon demonstration satisfactory to the Department that the hospital meets the criteria in 105 CMR 130.1400 through 130.1413.

130.1404: Stroke Service Director or Coordinator

The hospital shall designate a licensed physician with acute stroke expertise, who can represent the Primary Stroke Service and evaluate the hospital's capabilities to provide the required services, as the Stroke Service Director or Coordinator.

130.1405: Written Care Protocols

(A) The hospital shall develop and implement written care protocols for acute stroke. Such protocols shall include both the emergency and post-admission care of acute stroke patients by a multidisciplinary team. The hospital shall treat eligible patients according to its written care protocols consistent with time targets acceptable to the Department. These protocols shall address issues such as stabilization of vital functions, initial diagnostic tests, and use of medications (including but not limited to intravenous tissue-type plasminogen activator (t-PA) treatment), as applicable. These protocols shall be based on previously published guidelines or developed by a multidisciplinary team organized by the Stroke Service. Written care protocols for acute stroke shall be available in the Emergency Department (ED) and other areas likely to evaluate and treat patients with acute stroke.

(B) Emergency Department (ED) Stroke Protocols

1. The hospital shall develop and implement written protocols for triage and treatment of patients presenting with symptoms of acute stroke in the Emergency Department (e.g., use of thrombolytic therapy, management of increased intracranial pressure and blood pressure and post-thrombolysis management plan, as applicable).
2. The protocols shall include a method for communicating effectively with Emergency Medical Service (EMS) personnel in the pre-hospital setting during transportation of a patient with symptoms of acute stroke. The ED must be able to efficiently prepare for the arrival, to receive, and to triage patients with symptoms of acute stroke arriving via EMS transportation.

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Data Center means an organization approved by the Department to receive, process, analyze, and report on patient-specific outcome data submitted by hospitals with a designated Primary Stroke Service.

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3. The hospital shall develop and implement a specific, well-organized system for promptly notifying and activating the Acute Stroke Team to evaluate patients presenting with symptoms of acute stroke.

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(C) Post-Admission Care Protocols

The hospital shall develop and implement written protocols for the post-admission care of acute stroke patients.

130.1406: Neuroimaging Services

(A) The hospital shall have the ability to promptly perform brain computed tomography (CT) or magnetic resonance imaging (MRI) scans consistent with time targets acceptable to the Department.

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(B) The hospital shall provide prompt interpretation after study completion by a physician with experience in acute stroke neuroimaging, consistent with time targets acceptable to the Department. Neuroimaging interpretation may be provided directly by a staff physician at the hospital or by contractual arrangement with consultant physician(s). Physicians providing neuroimaging interpretation shall be available in the hospital or through remote access (e.g., teleradiology).

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130.1407: Other Imaging and Electrocardiogram Services

The hospital shall have the ability to promptly perform and evaluate chest x-rays and electrocardiograms consistent with time targets acceptable to the Department.

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130.1408: Laboratory Services

The hospital shall have the ability to promptly perform and evaluate routine serum chemistry, hematology and coagulation studies for acute stroke patients, consistent with time targets acceptable to the Department.

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130.1409: Neurosurgical Services

(A) The hospital shall develop and implement written protocols for patient access to neurosurgical evaluation and/or intervention within a reasonable period of time, which may include transfer to another hospital, consistent with time targets acceptable to the Department.

(B) If the written protocol includes the transfer of patients to another hospital, the hospital shall maintain a transfer agreement that describes the responsibilities of each hospital and is signed by the Stroke Service Director, the Medical Director of each hospital or his/her designee, and the Chief Executive Officer of each hospital or his/her designee.

130.1410: Quality Improvement

(A) The hospital shall implement and maintain an effective, data-driven quality assessment and performance improvement program for the Primary Stroke Service.

(B) The hospital shall collect and analyze data, as defined by the Department, on patients presenting to the ED with acute ischemic stroke who arrived within three hours of symptom onset, to identify opportunities for improvement in the service.

(C) The hospital shall submit data in a manner defined by the Department and in accordance with protocols established by the Department in an advisory bulletin.

130.1411: Continuing Health Professional Education

The hospital shall provide hospital-based staff education that addresses the needs of physicians, nurses, allied health professionals, and Emergency Medical Services (EMS) personnel. The program shall include ongoing formal training of ED and EMS system personnel in acute stroke prevention, diagnosis and treatment.

130.1412: Community Education

The hospital shall offer community education that provides information to the public regarding prevention of stroke, recognition of stroke symptoms, and/or treatment of stroke.

130.1413: Primary Stroke Service Review

The Primary Stroke Service protocols referenced in 105 CMR 130.1405 shall be reviewed and revised as necessary and at least annually by a committee designated by the governing body of the hospital and including the Stroke Service Director or Coordinator. The review must incorporate at a minimum the number of stroke patients, types of stroke evaluated, nature of any complications of thrombolytic therapy, and compliance with 105 CMR 130.1400 through 130.1413, including adherence to the time targets.

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(1) The hospital shall ensure that all data submitted by the hospital to the data center are in a de-identified electronic format and submitted on a timely basis. ¶
(2) The hospital shall develop, implement and maintain administrative procedures that ensure the confidentiality of the patient-specific data submitted to the data center. Primary Stroke Service data submitted by hospitals are subject to audit by the Department.¶

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